

REMARKS/ARGUMENTS

The claims have been amended to exclude certain polymorphisms discussed in references cited in the attached information disclosure statement. Applicants reserve the right to pursue these in a related case. This amendment should not be construed as acquiescence in any ground of rejection.

Sequence Listing

The Examiner has stated that this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the paper and computer readable form (CRF) copies of the substitute sequence listing contain different numbers of sequences. The Examiner has identified the paper copy, filed on December 11, 2001 as containing 30 sequences, and the CRF copy, filed November 4, 2002, as containing 77 sequences.

In response, the paper copy filed December 11, 2001 containing 30 sequences is correct. Applicants have no record of having submitted a CRF for this application containing 77 sequences. In any event, applicants now submit a further CRF containing 30 sequences that matches the paper copy filed December 11, 2001. This CRF contains 30 sequences as well. The enclosed CRF version of the substitute sequence listing is identical to the written copy of the sequence listing first filed on December 11, 2001, and thus contains no new matter.

Utility

The claims stand rejected under 35 USC 101 on the basis that the claimed invention lacks a specific substantial and credible utility, or in the alternative a well-established utility.

In response, it is submitted that at the very least the forensic application described at p. 13 of the specification is a specific, substantial, and credible utility. Applicants attach a number of articles describing the use of mitochondrial polymorphisms in forensics. Isenberg et al., Forensic Science Communication (1999) review use of mitochondrial DNA in forensic analysis by the FBI. The article notes that mitochondrial DNA is particularly useful for forensic

analysis because cells may contain many more copies of mitochondrial DNA than genomic DNA. Whereas diploid cells contain only two copies of genomic DNA, they contain 100's or 1000's of mitochondria, each of which contains several copies of a mitochondrial genome. The article explains that the greater copy number of mitochondrial DNA is particularly useful in situations where the amount of DNA in a sample is limited. Of course, this is very often the case when DNA is recovered from the scene of a crime (see p. 1 of article). The article also explains that the maternal transmission of mitochondrial DNA provides another advantage. In missing persons cases, a reference mitochondrial DNA sample for the missing person can be obtained from a maternal relative (see p. 2). The article notes that as of 1999, there were seven laboratories conducting forensic mitochondrial DNA testing and the FBI employed twelve people for this purpose (pp. 7-9). Similar information is provided by another reference, Ginther et al., Nature Genetics. 2, 135 (1992). This reference reports successfully typing of individuals from mitochondrial DNA extracted from teeth. The reference also notes advantages of performing forensic analysis on mitochondrial DNA relative to genomic: that is, higher copy number of mitochondrial DNA, maternal transmission, and ease of sequence determination due to the haploid state of the mitochondrial genome (see p. 137).

The above references show that forensic use of mitochondrial polymorphisms is a specific, substantial and credible utility. As the Examiner acknowledges, a substantial utility, means a "real world" use. Here, mitochondrial polymorphisms are being used for forensic analysis in the real world. As of 1999, there were at least seven laboratories performing this task, and the FBI alone employed 12 persons for this task. Evidence from such laboratories has been admitted in criminal trials in numerous jurisdictions (see Isenberg at p. 8). Therefore, mitochondrial forensic analysis is very much part of the real world.

The utility is also specific because mitochondrial polymorphisms are useful for forensics in situations in which genomic polymorphisms are not. As discussed in the references, mitochondrial polymorphisms can allow forensic analysis to be performed in circumstances when a sample contains too little DNA to permit analysis of genomic polymorphisms. Mitochondrial polymorphisms also allow forensic analysis of the polymorphic profile of a missing person based on a sample obtained from a maternal relative. Mitochondrial

polymorphisms are very few in number compared with genomic polymorphisms (the mitochondrial genome is only about 16.5 kb). Thus, the particular utility of mitochondrial polymorphisms for forensic analysis is not shared by the vast majority of polymorphisms in general.

It is acknowledged that the utility of the presently claimed polymorphisms for forensic analysis is not necessarily different from that of other mitochondrial polymorphisms not subject to the present claims. However, a "specific" utility cannot require that the utility of the claimed subject matter be unique to that subject matter and no other. Courts have routinely found structural similarity between a claimed compound and a prior art compound of known utility to be evidence that the claimed compound shares the utility of the prior art compound and thus satisfies the requirement for utility (see MPEP 2107.03 II). Therefore, the fact that a claimed compound has the same utility as a prior art compound does not disqualify the claimed compound from having a specific utility. Rather, courts have used the label "specific utility" in similar fashion to other labels such as "practical utility," or "substantial utility," as a means to assess real-world value (see MPEP 2107.01 I). As noted above, the particular utility of the claimed mitochondrial polymorphisms for forensic analysis in circumstances when genomic polymorphisms cannot be used is of undeniable value in the real world.

Finally, the utility of the claimed polymorphisms for performing forensic analysis is credible. As indicated in the office action, a utility is credible unless it is an inherently unbelievable undertaking or involves implausible scientific principles. Here, mitochondrial forensic analysis involves standard techniques of molecular biology (e.g., sequencing or probe hybridizations) and statistical analysis. These are mainstream textbook principles. Moreover, forensic mitochondrial analysis is in widespread use as evidenced by the attached references, and cannot therefore be said to be an inherently unbelievable undertaking.

The Examiner makes a number of comments regarding other utilities disclosed by the specification. Because one utility is sufficient to support patentability of the present claims, applicants have not addressed these remarks. This should not be construed as acquiescence with the Examiner's position.

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Amdt. dated October 27, 2003
Reply to Office Action of June 26, 2003

PATENT

Lack of enablement

The claims stand rejected for alleged lack of enablement. The rejection is based on the same rationale as the rejection for lack of utility. Applicants respond as above.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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